

UNITED STATES DISTRICT COURT  
FOR THE  
DISTRICT OF MASSACHUSETTS

In re: New England Compounding )  
Pharmacy, Inc., )  
 ) Civil Action No.: MDL 1:13-md-02419  
 ) (RWZ)  
All Cases Involving Specialty Surgery )  
Center )

**STIPULATED QUALIFIED PROTECTIVE [PROPOSED] ORDER REGARDING**  
**PLAINTIFFS' STEERING COMMITTEE'S SUBPOENA OF**  
**CUMBERLAND MEDICAL CENTER, INC.**

Whereas, the Plaintiffs' Steering Committee ("PSC"), the Defendants, and Cumberland Medical Center, Inc. ("CMC") have, through counsel, agreed to the entry of this Stipulated Qualified Protective Order Regarding Plaintiffs' Steering Committee's Subpoena of Cumberland Medical Center, Inc. ("QPO") pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and pursuant to regulations promulgated under the Health Insurance Portability and Accountability Act, as amended, to prevent unnecessary or unlawful disclosure or dissemination of confidential patient protected health information ("PHI"), financial information, and proprietary, confidential, and/or commercial information, the Court ORDERS that production and use of documents produced by CMC in response to PSC's subpoena proceed as follows:

**DEFINITIONS**

"Confidential Information" means documents over which CMC may claim attorney-client privilege, documents over which CMC may assert protection under the work-product doctrine, documents containing proprietary or confidential business information, documents containing PHI or financial information of patients who are not plaintiffs in the MDL matter, or documents containing PHI or financial information of CMC employees.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, codified primarily at 18, 26 & 42 U.S.C.

“PHI” means protected health information, as that term is used in HIPAA and the Privacy Standards defined in 45 C.F.R. § 160 & 164.

“Signatories” means all parties to this litigation, their attorneys, and their non-attorney staff and experts retained by any party, and all non-parties that a court may subsequently recognize as a signatory of this Qualified Protective Order.

### **PRE-PRODUCTION FORENSIC ANALYSIS**

1. CMC shall produce the electronic repositories (seven hard-drives) purchased from Specialty Surgery Center (“SSC”), to LogicForce Consulting, LLC (“LogicForce”), as set forth in the mutually agreed Protocols for Review of Certain Responsive Hard-Drives in Cumberland’s Possession (“Review Protocols”), which are incorporated herein by reference. Prior to CMC’s production of the hard-drives, LogicForce will execute a Business Associate Agreement with CMC for the purposes of conducting a forensic inspection and analysis of the hard-drives in accordance with the Review Protocols. By providing said electronic repositories to LogicForce, CMC is not waiving any claims of privilege, including attorney-client communication, or any other state or federal privilege that may be applicable and could have been asserted in the absence of disclosure to LogicForce.

2. LogicForce will conduct a forensic analysis and inspection of the seven-hard drives purchased by CMC from SSC as part of an Asset Purchase in 2014, in accordance with the terms and provisions set forth in the Review Protocols.

3. To the extent any documents containing PHI or other Confidential Information are produced to Signatories, Signatories agree to be bound by this Order.

**HIPAA TERMS AND LIMITATIONS**

4. The Signatories are familiar with HIPAA and the Privacy Standards.
5. The Signatories recognize that PSC's subpoena issued and served upon CMC seeks information that may include PHI.
6. Accordingly, the Signatories recognize that documents containing PHI produced by CMC may be further disseminated and transmitted to the Signatories, third-parties, and non-parties.
7. Notwithstanding federal or state law limiting the Signatories and CMC's authority to disclose PHI, CMC is permitted to release all PHI in its possession, which is currently stored on seven hard-drives in the possession, custody, and control of CMC, subject to the Review Protocols between the PSC and CMC, in response to the subpoena issued by the PSC on CMC on January 29, 2016, provided that the PHI is relevant to the issues presented in this litigation.
8. The Signatories are permitted to use the PHI in any manner that is reasonably connected with this lawsuit. This includes, but is not limited to, disclosures to the parties, their attorneys of record, the attorney's firms (i.e., attorneys, support staff, agents, and consultants) the parties insurers, experts, consultants, court personnel, court reporters, trial consultants, jurors, and other entities involved in the litigation process. The Signatories agree not to use or disclose any PHI produced by CMC in response to PSC's subpoena in this lawsuit for any other purpose or in any other proceeding.

9. The Signatories agree that within 90 days of the issuance of a final order, or the extinguishment of all appeals, all Signatories that obtained PHI produced by CMC in response to PSC's subpoena during the course of this lawsuit shall return to CMC or shall destroy said PHI.

**OTHER CONFIDENTIAL MATERIAL**

11. Prior to being permitted access to "Confidential Information" subject to this Order, a qualified person, i.e., (i) parties to this action including employees; (ii) counsel for the parties to this action, including office associates, paralegals, and clerical employees; (iii) witnesses, experts, consultants and other persons consulted or retained in connection with this litigation and who have agreed to be bound by the terms of this Order; and/or (iv) the parties' insurance adjusters (hereinafter collectively, "Qualified Person"), shall sign a Certification in the form attached hereto as **Exhibit A** stating that he/she has read and understands the terms of this Protective Order and that he/she will abide by them. The original of each Certification shall be retained by Counsel until the litigation is completed.

12. Each Qualified Person agrees to submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order, either prior to or following the completion of this action. Jurisdiction is to be retained by this Court after final determination for purposes of enabling the parties or CMC to apply to the Court at any time for such direction or further decree as may be appropriate for the construction or enforcement of this Order.

13. This Order initially protects from disclosure all documents that are produced by CMC in response to PSC's subpoena and which are designated "Confidential." Upon delivery of any document or other information so designated, any Signatory may, within ninety days of delivery of the document or other information, send a letter to CMC challenging any such designations by indicating by bates number range(s) or other sufficient identifying information

precisely which document(s) the challenging party asserts are not in fact "confidential." The parties shall confer in a good faith attempt to informally resolve the dispute. If such attempt is unsuccessful, the designating party shall by informal letter to the Court move for a protective order regarding any designation(s) in question (the "Motion Letter"), enclosing, where appropriate, the documents challenged for in camera review. The opposing party may trigger a time period in which a Motion Letter must be sent by sending a certified letter to the designating party stating that, in the opposing party's opinion, an impasse regarding designations has been reached (an "Impasse Letter"). Within thirty days after receipt by the designating party of an Impasse Letter, the designating party must transmit the Motion Letter to the Court. The documents challenged hereunder retain their status as "Confidential Information" hereunder unless and until the Court orders that they be released from such status.

14. If, during the course of motion practice, the Signatories seek to introduce a document identified as "Confidential Information," and stamped "Confidential" the party seeking to introduce the document shall notify CMC of its intent to introduce the same seven (7) days prior to introducing the document. The Signatory seeking to introduce the document take all necessary steps to obtain the Court's leave to file the document under seal. The foregoing stated, CMC retains the right to seek other appropriate relief from the Court including a protective order denying the introduction of Confidential Information, and CMC shall file for such relief within seven (7) days of notice of the Signatory's intent to introduce the Confidential Information.

15. If, at the time of trial, counsel for any of the parties attempts to introduce into evidence or use in cross-examination any Confidential Information, whether as part of a document or deposition testimony or otherwise, counsel for CMC may request the Court to

preserve the confidentiality of the Confidential Information to the extent and by means the Court deems necessary and appropriate, and any party may oppose such a request. Nothing in this paragraph, or this Order, shall be construed to prevent otherwise admissible evidence from being presented to the judge, jury, and/or an appellate court. Further, nothing in this paragraph or Order shall be construed to prevent or otherwise limit an expert from providing opinions, reports, and/or testimony based upon reliance (in whole or in part) upon Confidential Information. It is anticipated that the Court may preserve the confidentiality of Confidential Information through appropriate instructions to the jury.

17. For all Confidential Information other than PHI subject to the terms of paragraphs one through seven, upon the final conclusion (including any appeals) of this action, all Signatories and Qualified Persons and their counsel shall return all Confidential Information (and all copies thereof) to CMC (shipping costs to be borne by Signatory or their counsel) or confirm in writing that all PHI and Confidential Information has been destroyed.

A copy of this Protective Order shall be served on all counsel within \_\_\_\_ days of its entry.

So ORDERED on this \_\_\_\_\_ day of \_\_\_\_\_, 2016.

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United States District Court Judge

**EXHIBIT A**  
**UNITED STATES DISTRICT COURT**  
**FOR THE**  
**DISTRICT OF MASSACHUSETTS**

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Pharmacy, Inc., )  
 ) Civil Action No.: MDL 1:13-md-02419  
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All Cases Involving Specialty Surgery )  
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**EXHIBIT A TO STIPULATED QUALIFIED PROTECTIVE ORDER**

I, the undersigned, acknowledge that I have read the Stipulated Qualified Protective Order entered in New England Compounding Pharmacy, Inc., Case No. MDL 1:13-md-02419 (RWZ), understand the terms thereof, and agree to be bound by such terms, and to be subject to the jurisdiction of this Court for enforcement of all terms of the Stipulated Qualified Protective Order. I will use the materials subject to this Stipulated Qualified Protective Order solely for purposes of this litigation in accordance with the terms of such Stipulated Qualified Protective Order and agree to fully cooperate with respect to the protection of such materials in accordance with the terms of this Stipulated Qualified Protective Order.

AGREED this \_\_\_\_\_ day of \_\_\_\_\_, 201\_.

Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Address: \_\_\_\_\_